

# EXHIBIT J



Report and Recommendation (Dkt 96), the parties reserve their objections to, and any right to appeal, such claim constructions.

**ARTICLE 1**  
**PRELIMINARY INSTRUCTIONS**

**1.1 PRELIMINARY INSTRUCTIONS (AFTER JURY IS SWORN IN)**

**MEMBERS OF THE JURY:**

You have now been sworn as the jury to try this case. As the jury you will decide the disputed questions of fact.

As the Judge, I will decide all questions of law and procedure. From time to time during the trial and at the end of the trial, I will instruct you on the rules of law that you must follow in making your decision.

Soon, the lawyers for each of the parties will make what is called an opening statement. Opening statements are intended to assist you in understanding the evidence. What the lawyers say is not evidence.

After the opening statements, the plaintiff will call witnesses and present evidence. Then, the defendant will have an opportunity to call witnesses and present evidence. After the parties' main case is completed, the plaintiff may be permitted to present rebuttal evidence. After all the evidence is completed, the lawyers will again address you to make final arguments. Then I will instruct you on the applicable law. You will then retire to deliberate on a verdict.

Keep an open mind during the trial. Do not decide any fact until you have heard all of the evidence, the closing arguments, and my instructions.

Pay close attention to the testimony and evidence. If you would like to take notes during the trial, you may do so. If you do take notes, be careful not to get so involved in note taking that you become distracted and miss part of the testimony. Your notes are to be used only as aids to your memory, and if your memory should later be different from your notes, you should rely on your memory and not on your notes. If you do not take notes, rely on your own independent memory of the testimony. Do not be unduly influenced by the notes of other jurors. A juror's notes are not entitled to any greater weight than the recollection of each juror concerning the testimony. Even though the court reporter is making stenographic notes of everything that is said, a typewritten copy of the testimony will not be available for your use during deliberations. On the other hand, any exhibits will be available to you during your deliberations.

Until this trial is over, do not discuss this case with anyone and do not permit anyone to discuss this case in your presence. Do not discuss the case even with the other jurors until all of the jurors are in the jury room actually deliberating at the end of the case. If anyone should attempt to discuss this case or to approach you concerning the case, you should inform the Court immediately. Hold yourself completely apart from the people involved in the case—the parties, the witnesses, the attorneys and persons associated with them. It is important not only that you be fair and impartial but that you also appear to be fair and impartial.

Do not make any independent investigation of any fact or matter in this case. You are to be guided solely by what you see and hear in this trial. Do not learn anything about the case from any other source.

During the trial, it may be necessary for me to confer with the lawyers out of your hearing or to conduct a part of the trial out of your presence. I will handle these matters as briefly and as conveniently for you as I can, but you should remember that they are a necessary part of any trial.

**[Source: Fifth Circuit Pattern Jury Instructions – Civil, § 1.1 (2006) (modified to: (1) delete the last sentence of this instruction – “It is now time for the opening statements” – to allow the Court to provide additional preliminary instructions prior to opening statements, (2) permit the jury to take notes; and (3) remove references to public coverage of trial).]**

## 1.2 WHAT A PATENT IS AND HOW ONE IS OBTAINED

This case involves a dispute relating to a United States patent. Before summarizing the positions of the parties and the issues involved in the dispute, let me take a moment to explain what a patent is and how one is obtained.

Patents are granted by the United States Patent and Trademark Office (sometimes called “the PTO”). A valid United States patent gives the patent holder the right for up to 20 years from the date the patent application was filed to prevent others from making, using, offering to sell, or selling the patented invention within the United States, or from importing it into the United States, without the patent holder’s permission. A violation of the patent holder’s rights is called infringement. The patent holder may try to enforce a patent against persons believed to be infringers by a lawsuit filed in federal court.

The process of obtaining a patent is called patent prosecution. To obtain a patent, one must first file an application with the PTO. The PTO is an agency of the Federal Government and employs trained Examiners who review applications for patents. The application includes what is called a “specification,” which contains a written description of the claimed invention telling what the invention is, how it works, how to make it, and how to use it. The specification concludes with one or more numbered sentences. These are the patent “claims.” When the patent is eventually granted by the PTO, the claims define the boundaries of its protection and give notice to the public of those boundaries.

After the applicant files the application, an Examiner reviews the application to determine whether or not the claims are patentable (appropriate for patent protection) and whether or not the specification adequately describes the invention claimed. In examining a patent application, the Examiner reviews certain information about the state of the technology at the time the application was filed. The PTO searches for and reviews information that is publicly available or that is submitted by the applicant. This information is called “prior art.” The Examiner reviews this prior art to determine whether or not the invention is truly an advance over the state of the art at the time. Prior art is defined by law, and I will give you, at a later time during these instructions, specific instructions as to what constitutes prior art. However, in general, prior art includes information that demonstrates the state of technology that existed before the claimed invention was made or before the application was filed. A patent lists the prior art that the Examiner considered; this list is called the “cited references.”

After the prior art search and examination of the application, the Examiner informs the applicant in writing of what the Examiner has found and whether the Examiner considers any claim to be patentable and, thus, would be “allowed.” This writing from the Examiner is called an “Office Action.” If the Examiner rejects the claims, the applicant has an opportunity to respond to the Examiner to try to persuade the Examiner to allow the claims, and to change the claims or to submit new claims. This process may go back and forth for some time until the Examiner is satisfied that the application meets the requirements for a patent and the application issues as a patent, or that the application should be rejected and no patent should issue. Sometimes, patents are issued after appeals within the PTO or to a court. The papers generated during these communications between the Examiner and the applicant are called the “prosecution history.”

The fact that the PTO grants a patent does not necessarily mean that any invention claimed in the patent, in fact, deserves the protection of a patent. For example, the PTO may not have had available to it all other prior art that will be presented to you. A person accused of

infringement has the right to argue here in federal court that a claimed invention in the patent is invalid because it does not meet the requirements for a patent. It is your job to consider the evidence presented by the parties and determine independently whether or not Virtus has proven that the patent is invalid.

I will now have a short video played for you that provides some additional background information about patents. The video references a sample patent, of which you should all now have a copy..

[Play “An Introduction to the Patent System” available at <https://www.youtube.com/watch?v=-q0mLrvw1Yc>]

[Source: The Federal Circuit Bar Association Model Patent Jury Instructions, § A.1 (2014)].

### 1.3 SUMMARY OF CONTENTIONS

To help you follow the evidence, I will now give you a summary of the positions of the parties.

The parties in this case are Mission and Virtus. The case involves United States Patent No. 6,521,247, which issued on February 18, 2003 to a pharmaceutical company named Warner Chilcott and was subsequently sold to Mission.

For your convenience, the parties and I will often refer to this patent number 6,521,247 by the last three numbers of the patent number, namely, as the “‘247 patent.”

Mission filed suit in this court seeking money damages from Virtus on two separate grounds. First, Mission alleges that Virtus infringes the ‘247 patent by selling in the United States products that Mission argues are covered by claim 17 of the ‘247 patent. The products that are alleged to infringe are Virtus’s Natalvirt CA, Natalvirt 90 DHA, and Natalvirt FLT. Second, Mission alleges that Virtus has falsely advertised those products.

Virtus denies that it has infringed claim 17 of the ‘247 patent. Virtus also argues that claim 17 is invalid. I will instruct you later as to the ways in which a patent may be invalid. In general, however, a patent is invalid if it is not new or is obvious in view of the state of the art at the relevant time, or if the description in the patent does not meet certain requirements. Virtus also denies that it has engaged in any false advertising.

Your job will be to decide whether or not claim 17 of the ‘247 patent has been infringed and whether or not that claim is invalid. If you decide that claim 17 of the ‘247 patent has been infringed and is not invalid, you will then need to decide any money damages to be awarded to Mission to compensate it for the infringement. You will also need to make a finding as to whether the infringement was willful. If you decide that any infringement was willful, that decision should not affect any damages award you give. I will take willfulness into account later.

In addition, you will need to decide whether Virtus has engaged in false advertising. If you decide that Virtus has engaged in false advertising, you will need to decide any money damages to be awarded to Mission.

[Source: The Federal Circuit Bar Association Model Patent Jury Instructions, § A.2 (2014)].



#### 1.4 PATENT AT ISSUE

[The Court should show the jury the patent at issue and point out the parts, which include the specification, drawings, the original claims, the reexamined claims, and the claims at issue (claim 17).]

The ‘247 patent has been through a procedure called reexamination. Reexamination is a procedure where a person or company who believes that a patent is invalid may ask the PTO to “reexamine” or reconsider the issued patent to determine whether the patent should, in fact, be issued. In the case of the ‘247 Patent, a person challenged the validity of the ‘247 patent by submitting prior art to the PTO that the PTO had not considered during the initial reexamination. The PTO determined that the ‘247 patent’s claims were not patentable as they were initially written, but were patentable after being amended by Mission. The reexamination certificate at the back of the ‘247 patent shows the claims that the PTO determined were patentable at the conclusion of the reexamination. You will notice that claim 1 has certain language in italics. That language was added during reexamination. Claim 17, has some language in italics that was added during reexamination, and other language that has been bracketed. The bracketed language was deleted during reexamination.

[The Court may wish to hand out its claim constructions and the glossary at this time. If the claim constructions are handed out, the following instruction should be read:]

I have already determined the meaning of the claims of the ‘247 patent. You have been given a document reflecting those meanings. For a claim term for which I have not provided you with a definition, you should apply the ordinary meaning. You are to apply my definitions of these terms throughout this case. However, my interpretation of the language of the claims should not be taken as an indication that I have a view regarding issues such as infringement and invalidity. Those issues are yours to decide. I will provide you with more detailed instructions on the meaning of the claims before you retire to deliberate your verdict.

[Source: The Federal Circuit Bar Association Model Patent Jury Instructions, § A.3 (2014)].

## 1.5 OVERVIEW OF APPLICABLE LAW

In this case, you will have to decide five issues:

- 1) Whether Mission has proven that Virtus infringed claim 17 of the ‘247 Patent;
- 2) Whether Virtus has proven that claim 17 of the ‘247 patent is invalid;
- 3) If you find that Virtus infringed claim 17 of the ‘247 Patent, whether Virtus’s infringement was willful;
- 4) Whether Virtus falsely advertised its products; and
- 5) If you find that Virtus infringed claim 17 of the ‘247 patent or has falsely advertised its products, what amount of damages Mission is entitled to.

In deciding the issues I just discussed, you will be asked to consider specific legal standards. I will give you an overview of those standards now and will review them in more detail before the case is submitted to you for your verdict.

The first issue you will be asked to decide is whether Virtus has infringed claim 17 of the ‘247 patent by selling certain products in the United States. To prove infringement, Mission must show, by a preponderance of the evidence, that the Virtus products meet every element of claim 17, as well as every element of claim 1 from which it depends. I will provide you with more detailed instructions on the requirements for infringement at the conclusion of the case.

Another issue you will be asked to decide is whether the ‘247 patent is invalid. A patent may be invalid for a number of reasons, including because it claims subject matter that is not new or is obvious. For a claim to be invalid because it is not new, Virtus must show, by clear and convincing evidence, that all of the elements of a claim are present in a single previous device or method, or sufficiently described in a single previous printed publication or patent. We call these “prior art.” If a claim is not new, it is said to be anticipated.

Another way that a claim may be invalid is that it may have been obvious. Even though every element of a claim is not shown or sufficiently described in a single piece of “prior art,” the claim may still be invalid if it would have been obvious to a person of ordinary skill in the field of technology of the patent at the relevant time. You will need to consider a number of questions in deciding whether the invention(s) claimed in the ‘247 patent are obvious. I will provide you detailed instructions on these questions at the conclusion of the case.

[A patent claim may also be invalid if it is indefinite. A patent must be precise enough to afford clear notice of what is claimed. A patent claim is invalid for indefiniteness if, read in light of the specification delineating the patent and the prosecution history, it fails to inform those skilled in the art about the scope of the invention with reasonable certainty.]<sup>1</sup>

A patent may also be invalid if its description in the specification does not meet certain requirements. To be valid, a patent must meet the “written description” requirement. In order to meet this written description requirement, the description of the invention in the specification portion of the patent must be detailed enough to demonstrate that the applicant actually possessed

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<sup>1</sup> The parties remain in discussions regarding the appropriateness of instructions related to indefiniteness. To the extent that any revisions are required the parties will submit them to the Court prior to the Pretrial Conference and to the extent any disagreements remain, the parties will indicate the same and be prepared to address their respective contentions at the Pretrial Conference.

the invention as broadly as claimed in the claims of the issued patent. The disclosure of a patent must also meet the “enablement” requirement. To meet this requirement, the description in the patent has to be sufficiently full and clear to have allowed persons of ordinary skill in the field of technology of the patent to make and use the invention without undue experimentation, at the time the patent application was originally filed.

You will also be asked to determine whether Virtus falsely advertised its products. To prove that Virtus engaged in false advertising, Mission must show, among other things, that Virtus made false or misleading statements of fact about its products, that the statements actually deceived or had the capacity to deceive a substantial segment of potential consumers, and that it was a material deception in that it was likely to influence a consumer’s purchasing decision. I will provide you with more detailed instructions on the requirements for false advertising at the conclusion of the case.

If you decide that claim 17 of the ‘247 patent has been infringed and is not invalid, or that Virtus has falsely advertised its products, you will then need to decide any money damages to be awarded to Mission to compensate it for the infringement or false advertisement. A damages award for infringement should put Mission in approximately the same financial position that it would have been in had the infringement not occurred, but in no event may the damages award be less than what Mission would have received had it been paid a reasonable royalty. I will instruct you later on the meaning of a reasonable royalty. The damages you award are meant to compensate Mission and not to punish Virtus. You may not include in your award any additional amount as a fine or penalty, above what is necessary to compensate Mission for the infringement or false advertisement, in order to punish Virtus. I will give you more detailed instructions on the calculation of damages at the conclusion of the case.

[Sources: The Federal Circuit Bar Association Model Patent Jury Instructions, § A.4 (2014); *Nautilus, Inc. v. Biosig Instruments, Inc.*, 134 S. Ct. 2120, 189 L. Ed. 2d 37 (U.S. 2014); and *Pizza Hut, Inc. v. Papa John’s Int’l, Inc.*, 227 F.3d 489 (5th Cir. 2000)].

## 1.6 OUTLINE OF TRIAL

The trial will now begin. First, each side may make an opening statement. An opening statement is not evidence. It is simply an opportunity for the lawyers to explain what they expect the evidence will show.

There are two standards of proof that you will apply to the evidence, depending on the issue you are deciding. On some issues, you must decide whether certain facts have been proven by a preponderance of the evidence. A preponderance of the evidence means that the fact that is to be proven is more likely true than not, i.e., that the evidence in favor of that fact being true is sufficient to tip the scale, even if slightly, in its favor. On other issues that I will identify for you, you must use a higher standard and decide whether the fact has been proven by clear and convincing evidence, i.e., that you have been left with a clear conviction that the fact has been proven.

These standards are different from what you may have heard about in criminal proceedings where a fact must be proven beyond a reasonable doubt. On a scale of these various standards of proof, as you move from preponderance of the evidence, where the proof need only be sufficient to tip the scale in favor of the party proving the fact, to beyond a reasonable doubt, where the fact must be proven to a very high degree of certainty, you may think of clear and convincing evidence as being between the two standards.

After the opening statements, Mission will present its evidence in support of its contention that claim 17 of the ‘247 patent has been and continues to be infringed by Virtus and that the infringement has been and continues to be willful. To prove infringement of any claim, Mission must persuade you that it is more likely than not that Virtus has infringed that claim. To persuade you that any infringement was willful, Mission must prove that the infringement was willful by clear and convincing evidence. Mission will also present its evidence in support of its false advertising claim.

Virtus will then present its evidence that claim 17 of the ‘247 patent is invalid. To prove invalidity of a claim, Virtus must persuade you by clear and convincing evidence that the claim is invalid. In addition to presenting its evidence of invalidity, Virtus will put on evidence responding to Mission’s proof of infringement, willfulness, and false advertising.

Mission may then put on additional evidence responding to Virtus’s evidence that claim 17 of the ‘247 patent is invalid, and to offer any additional evidence of infringement, willfulness, or false advertising. This is referred to as “rebuttal” evidence. Mission’s “rebuttal” evidence may respond to any evidence offered by Virtus.

Finally, Virtus may have the option to put on its “rebuttal” evidence to support its contentions as to the validity of claim 17 of the ‘247 patent by responding to any evidence offered by Mission on that issue.

After the evidence has been presented, the attorneys will make closing arguments and I will give you final instructions on the law that applies to the case. These closing arguments by the attorneys are not evidence. After the closing arguments and instructions, you will then decide the case.

It is now time for the opening statements.

[Source: The Federal Circuit Bar Association Model Patent Jury Instructions, § A.5 (2014)].

## **ARTICLE 2**

### **INSTRUCTIONS AT CLOSE OF EVIDENCE**

#### **2.1 SUMMARY OF CONTENTIONS**

As I did at the start of the case, I will first give you a summary of each side's contentions in this case. I will then provide you with detailed instructions on what each side must prove to win on each of its contentions.

I will first address Mission's patent infringement claim. After I address Mission's patent infringement claim, I will address Mission's false advertising claim.

As I previously told you, Mission seeks money damages from Virtus for allegedly infringing the '247 patent by selling products that Mission argues are covered by claim 17 of the '247 patent. Claim 17 is the asserted claim of the '247 patent and includes the elements of claim 1, from which it depends. The products that are alleged to infringe are Natalvirt CA, Natalvirt 90 DHA, and Natalvirt FLT.

Virtus denies that it has infringed the asserted claim of the '247 patent and argues that, in addition, claim 17 is invalid.

Your job is to decide whether Virtus has infringed the asserted claim of the '247 patent and whether the asserted claim is invalid. If you decide that the asserted claim of the '247 patent has been infringed and is not invalid, you will then need to decide any money damages to be awarded to Mission to compensate it for the infringement. You will also need to make a finding as to whether the infringement was willful. If you decide that any infringement was willful, that decision should not affect any damages award you make. I will take willfulness into account later.

[Source: The Federal Circuit Bar Association Model Patent Jury Instructions, § B.1 (2014)].

## 2.2 THE ROLE OF THE CLAIMS OF A PATENT

Before you can decide many of the issues in this case, you will need to understand the role of patent “claims.” The patent claims are the numbered sentences at the end of each patent. The claims are important because it is the words of the claims that define what a patent covers. The figures and text in the rest of the patent provide a description and/or examples of the invention and provide a context for the claims, but it is the claims that define the breadth of the patent’s coverage. Each claim is effectively treated as if it were a separate patent, and each claim may cover more or less than another claim. Therefore, what a patent covers depends, in turn, on what each of its claims covers.

You will first need to understand what each claim covers in order to decide whether or not there is infringement of the claim and to decide whether or not the claim is invalid. The law says that it is my role to define the terms of the claims and it is your role to apply my definitions to the issues that you are asked to decide in this case. Therefore, as I explained to you at the start of the case, I have determined the meaning of the claims and I will provide to you my definitions of certain claim terms. You must accept my definitions of these words in the claims as being correct. It is your job to take these definitions and apply them to the issues that you are deciding, including the issues of infringement and validity.

[Source: The Federal Circuit Bar Association Model Patent Jury Instructions, § B.2(2.1) (2014)].

## 2.3 HOW A CLAIM DEFINES WHAT IT COVERS

I will now explain how a claim defines what it covers.

A claim sets forth, in words, a set of requirements. Each claim sets forth its requirements in a single sentence. If a product meets each of these requirements, then it is covered by the claim.

There can be several claims in a patent. Each claim may be narrower or broader than another claim by setting forth more or fewer requirements. The coverage of a patent is assessed claim-by-claim. In patent law, the requirements of a claim are often referred to as “claim elements” or “claim limitations.” When a thing (such as a product or a process) meets all of the requirements of a claim, the claim is said to “cover” that thing, and that thing is said to “fall” within the scope of that claim. In other words, a claim covers a product or process where each of the claim elements or limitations is present in that product or process.

Sometimes the words in a patent claim are difficult to understand, and therefore it is difficult to understand what requirements these words impose. It is my job to explain to you the meaning of the words in the claims and the requirements these words impose.

As I just instructed you, there are certain specific terms that I have defined and you are to apply the definitions that I provide to you.

By understanding the meaning of the words in a claim and by understanding that the words in a claim set forth the requirements that a product or process must meet in order to be covered by that claim, you will be able to understand the scope of coverage for each claim. Once you understand what each claim covers, then you are prepared to decide the issues that you will be asked to decide, such as infringement and invalidity.

[Source: The Federal Circuit Bar Association Model Patent Jury Instructions, § B.2(2.2) (2014)].



## 2.4 INDEPENDENT AND DEPENDENT CLAIMS

The asserted claim of the '247 patent is a “dependent” claim. To understand what a dependent claim is, it is helpful to first understand what an independent claim is. An “independent claim” sets forth all of the requirements that must be met in order to be covered by that claim. Thus, it is not necessary to look at any other claim to determine what an independent claim covers. In this case, and for example, claim 1 of the '247 patent is an independent claim.

Claims that are not independent claims are “dependent claims.” A dependent claim does not itself recite all of the requirements of the claim but refers to another claim for some of its requirements. In this way, the claim “depends” on another claim. A dependent claim incorporates all of the requirements of the claim to which it refers. In this case, claim 17 depends from claim 1, and therefore incorporates all of the requirements of claim 1. The dependent claim then adds its own additional requirements. To determine what a dependent claim covers, it is necessary to look at both the dependent claim and any other claim to which it refers. A product that meets all of the requirements of both the dependent claim and the claim(s) to which it refers is covered by that dependent claim.

[Source: The Federal Circuit Bar Association Model Patent Jury Instructions, § B.2(2.2a) (2014)].

## 2.5 CLAIM INTERPRETATION

I will now explain to you the meaning of some of the words of the claims in this case. In doing so, I will explain some of the requirements of the claims. As I have previously instructed you, you must accept my definition of these words in the claims as correct. For any words in the claim for which I have not provided you with a definition, you should apply their common meaning. You should not take my definition of the language of the claims as an indication that I have a view regarding how you should decide the issues that you are being asked to decide, such as infringement and invalidity. These issues are yours to decide.

Claim 1 says: A nutritional supplement for a human, the supplement comprising folic acid, a first pharmaceutically acceptable iron compound selected to be slowly dissolving and a second, different pharmaceutically acceptable iron compound selected to be rapidly dissolving, wherein said first pharmaceutically acceptable iron compound is carbonyl iron.

Claim 17 says: The nutritional supplement of claim 1, wherein the rapidly dissolving iron compound is selected from the group consisting of ferrous fumarate, ferrous sulfate, ferrous gluconate, ferric ammonium citrate, and iron-protein succinylate.

The first term I will construe is the term “iron compound.” As used in the claims of the ‘247 patent, the term “iron compound” does not include excipients, inactive chemicals, and fillers.

The second term I will construe is “a second, different pharmaceutically acceptable iron compound.” That term in claim 1 means “an iron compound that is not carbonyl iron.”

The third term I will construe is “rapidly dissolving.” An iron compound characterized as “rapidly dissolving”

(1) must “have a solubility in water at 25° C. greater than about 1 part in 1000 (i.e.,] 1 part of the iron compound is soluble in fewer than 1000 parts of water),” and

(2) “will substantially saturate or completely dissolve in a sufficient volume of saliva or a gastrointestinal fluid in less than about 3 hours, preferably less than about 1 hour;” and

the chemical compound ferrous gluconate is rapidly dissolving.

The fourth term I will construe is “selected to be.” The term “selected to be rapidly dissolving” means the iron compound is chosen from a group of alternatives for the reason it will (or, because it will) rapidly dissolve in the future.

[Source: The Federal Circuit Bar Association Model Patent Jury Instructions, § B.2(2.3) (2014)].

## 2.6 INFRINGEMENT

I will now instruct you how to decide whether or not Virtus has infringed the ‘247 patent.

In this case, Mission has alleged that Virtus infringes the ‘247 patent by selling Natalvirt CA, Natalvirt 90 DHA, and Natalvirt FLT.

In order to prove infringement, Mission must prove that the requirements for infringement are met by a preponderance of the evidence, i.e., that it is more likely than not that all of the requirements of infringement have been proved. Specifically Mission must prove by a preponderance of the evidence, i.e., that it is more likely than not, that Virtus sold within the United States a product that meets all of the requirements of claim 17 and did so without Mission’s permission. You must compare the product with each and every one of the requirements of claim 17, which also includes all of the requirements of claim 1 from which it depends, to determine whether all of the requirements of claim 17 are met.

[Source: The Federal Circuit Bar Association Model Patent Jury Instructions, § B.3(3.1) (2014)].

## 2.7 WILLFUL INFRINGEMENT

In this case, Mission argues both that Virtus infringed and, further, that Virtus infringed willfully. If you have decided that Virtus has infringed, you must go on and address the additional issue of whether or not this infringement was willful.

Willfulness requires you to determine by clear and convincing evidence that Virtus acted recklessly.

To prove that Virtus acted recklessly, Virtus must prove two things by clear and convincing evidence:

The first part of the test is objective: the patent holder must persuade you that Virtus acted despite a high likelihood that Virtus's actions infringed a valid and enforceable patent. In making this determination, you may not consider Virtus's state of mind. Legitimate or credible defenses to infringement, even if not ultimately successful, demonstrate a lack of recklessness.

Only if you conclude that Virtus's conduct was reckless do you need to consider the second part of the test. The second part of the test does depend on the state of mind of Virtus. The patent holder must persuade you that Virtus actually knew or should have known that its actions constituted an unjustifiably high risk of infringement of a valid and enforceable patent. To determine whether Virtus had this state of mind, consider all facts which may include, but are not limited, to:

(1) Whether or not Virtus acted in accordance with the standards of commerce for its industry;

(2) Whether or not Virtus intentionally copied a product of Mission that is covered by the '247 patent;

(3) Whether or not there is a reasonable basis to believe that Virtus did not infringe or had a reasonable defense to infringement;

(4) Whether or not Virtus made a good-faith effort to avoid infringing the '247 patent, for example, whether Virtus attempted to design around the '247 patent; and

(5) Virtus argues it did not act recklessly because it relied on a legal opinion that advised Virtus that the its products did not infringe the '247 patent. You must evaluate whether the opinion was of a quality that reliance on its conclusions was reasonable.

[Source: The Federal Circuit Bar Association Model Patent Jury Instructions, § B.3(3.10) (2014)].

## 2.8 **INVALIDITY—BURDEN OF PROOF**

I will now instruct you on the rules you must follow in deciding whether or not Virtus has proven that claim 17 of the '247 patent is invalid. To prove that any claim of a patent is invalid, Virtus must persuade you by clear and convincing evidence, i.e., you must be left with a clear conviction that the claim is invalid.

[Source: The Federal Circuit Bar Association Model Patent Jury Instructions, § B.4(4.1) (2014)].

## 2.9 INDEFINITENESS<sup>2</sup>

The patent laws have requirements for the way in which patent claims are written. Patent claims must be precise enough that a person of ordinary skill in the field of the invention reading them has clear notice of what the claims cover and what they do not cover. Virtus contends that claims 1 and 17 of Mission's 247 patent are invalid because the language of the claims is indefinite. To succeed, Virtus must show by clear and convincing evidence that the claims fail to meet the law's requirements for clarity and precision.

In deciding whether the patent claims meet the definiteness requirement, you must consider the claims in light of the patent's specification and prosecution history from the viewpoint of a person having ordinary skill in the field of the invention at the time the provisional application was filed. The definiteness requirement is satisfied if the claims, viewed in light of the specification and prosecution history, inform those skilled in the art about the scope of the invention with reasonable certainty. The definiteness requirement, so understood, mandates clarity, while recognizing that absolute precision is unattainable.

[Source: *Nautilus, Inc. v. Biosig Instruments, Inc.*, 134 S. Ct. 2120, 189 L. Ed. 2d 37 (U.S. 2014)]

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<sup>2</sup> The parties remain in discussions regarding the appropriateness of instructions related to indefiniteness. To the extent that any revisions are required the parties will submit them to the Court prior to the Pretrial Conference and to the extent any disagreements remain, the parties will indicate the same and be prepared to address their respective contentions at the Pretrial Conference.

## 2.10 WRITTEN DESCRIPTION REQUIREMENT

The patent law contains certain requirements for the part of the patent called the specification. Virtus contends that claims 1 and 17 of Mission's 247 patent are invalid because the specification of the 247 patent does not contain an adequate written description of the invention. To succeed, Virtus must show by clear and convincing evidence that the specification fails to meet the law's requirements for written description of the invention. In the patent application process, the applicant may keep the originally filed claims, or change the claims between the time the patent application is first filed and the time a patent is issued. An applicant may amend the claims or add new claims. These changes may narrow or broaden the scope of the claims. The written description requirement ensures that the issued claims correspond to the scope of the written description that was provided in the original application.

In deciding whether the patent satisfies this written description requirement, you must consider the description from the viewpoint of a person having ordinary skill in the field of technology of the patent when the provisional application was filed. The written description requirement is satisfied if a person having ordinary skill reading the original patent application would have recognized that it describes the full scope of the claimed invention as it is finally claimed in the issued patent and that the inventor actually possessed that full scope by the filing date of the original application.

The written description requirement may be satisfied by any combination of the words, structures, figures, diagrams, formulas, etc., contained in the patent application. The full scope of a claim or any particular requirement in a claim need not be expressly disclosed in the original patent application if a person having ordinary skill in the field of technology of the patent at the time of filing would have understood that the full scope or missing requirement is in the written description in the patent application.

[Source: The Federal Circuit Bar Association Model Patent Jury Instructions, § B.4(4.2a) (2014)].

## 2.11 **ENABLEMENT**

The patent law contains certain requirements for the part of the patent called the specification. Virtus contends that claims 1 and 17 of Mission’s 247 patent are invalid because the specification does not contain a sufficiently full and clear description of how to make and use the full scope of the claimed invention. To succeed, Virtus must show by clear and convincing evidence that the 247 patent does not contain a sufficiently full and clear description of the claimed invention. To be sufficiently full and clear, the description must contain enough information to have allowed a person having ordinary skill in the field of technology of the patent to make and use the full scope of the claimed invention at the time the original patent application was filed. This is known as the “enablement” requirement. If a patent claim is not enabled, it is invalid.

In order to be enabling, the patent must permit persons having ordinary skill in the field of technology of the patent to make and use the full scope of the claimed invention at the time of original filing without having to conduct undue experimentation. However, some amount of experimentation to make and use the invention is allowable. In deciding whether a person having ordinary skill would have to experiment unduly in order to make and use the invention, you may consider several factors:

- (1) the time and cost of any necessary experimentation;
- (2) how routine any necessary experimentation is in the field of nutritional supplements;
- (3) whether the patent discloses specific working examples of the claimed invention;
- (4) the amount of guidance presented in the patent;
- (5) the nature and predictability of the field of nutritional supplements;
- (6) the level of ordinary skill in the field of nutritional supplements; and
- (7) the scope of the claimed invention.

No one or more of these factors is alone dispositive. Rather, you must make your decision whether or not the degree of experimentation required is undue based upon all of the evidence presented to you. You should weigh these factors and determine whether or not, in the context of this invention and the state of the art at the time of the original application, a person having ordinary skill would need to experiment unduly to make and use the full scope of the claimed invention.

[Source: The Federal Circuit Bar Association Model Patent Jury Instructions, § B.4(4.2b) (2014)].



## 2.12 INVALIDITY – PRIOR ART

Prior art may include items that were publicly known or that have been used or offered for sale, or references, such as publications or patents, that disclose the claimed invention or elements of the claimed invention. To be prior art, the item or reference must have been made, known, used, published, or patented either before the invention was made or more than one year before the filing date of the patent application. However, prior art does not include a publication that describes the inventor's own work and was published less than one year before the date of invention. [Where appropriate, add limitation that subject matter developed by another which qualifies as prior art only under one or more of subsections (e), (f), and (g) of 35 U.S.C. § 102 where the subject matter and the claimed invention were, at the time the claimed invention was made, owned by the same person, or subject to an obligation of assignment to the same person.]

For the claim to be invalid because it is not new, Virtus must show by clear and convincing evidence that all of the requirements of that claim were present in a single previous device or method that was known of, used, or described in a single previous printed publication or patent. We call these things “anticipating prior art.” To anticipate the invention, the prior art does not have to use the same words as the claim, but all of the requirements of the claim must have been disclosed, either stated expressly or implied to a person having ordinary skill in the art in the technology of the invention, so that looking at that one reference, that person could make and use the claimed invention.

[Source: The Federal Circuit Bar Association Model Patent Jury Instructions, § B.4.3(4.3a-1) (2014)].

## 2.13 INVALIDITY – OBVIOUSNESS

Even though an invention may not have been identically disclosed or described before it was made by an inventor, in order to be patentable, the invention must also not have been obvious to a person of ordinary skill in the field of technology of the patent at the time the invention was made.

Virtus may establish that a patent claim is invalid by showing, by clear and convincing evidence, that the claimed invention would have been obvious to persons having ordinary skill in the art at the time the invention was made in the field of nutritional supplements.

In determining whether a claimed invention is obvious, you must consider the level of ordinary skill in the field nutritional supplements that someone would have had at the time the provisional patent application was filed, the scope and content of the prior art, and any differences between the prior art and the claimed invention.

Keep in mind that the existence of each and every element of the claimed invention in the prior art does not necessarily prove obviousness. Most, if not all, inventions rely on building blocks of prior art. In considering whether a claimed invention is obvious, you may but are not required to find obviousness if you find that at the time of the patent's priority filing date there was a reason that would have prompted a person having ordinary skill in the field of nutritional supplements to combine the known elements in a way the claimed invention does, taking into account such factors as (1) whether the claimed invention was merely the predictable result of using prior art elements according to their known function(s); (2) whether the claimed invention provides an obvious solution to a known problem in the relevant field; (3) whether the prior art teaches or suggests the desirability of combining elements claimed in the invention; (4) whether the prior art teaches away from combining elements in the claimed invention; (5) whether it would have been obvious to try the combinations of elements, such as when there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions; and (6) whether the change resulted more from design incentives or other market forces. To find it rendered the invention obvious, you must find that the prior art provided a reasonable expectation of success. Obvious to try is not sufficient in unpredictable technologies.

In determining whether the claimed invention was obvious, consider each claim separately. Do not use hindsight, i.e., consider only what was known at the time of the patent's priority filing date.

In making these assessments, you should take into account any objective evidence (sometimes called "secondary considerations") that may shed light on the obviousness or not of the claimed invention, such as:

- a. Whether the invention was commercially successful as a result of the merits of the claimed invention (rather than the result of design needs or market-pressure advertising or similar activities);
- b. Whether the invention satisfied a long-felt need;
- c. Whether others had tried and failed to make the invention;
- d. Whether others invented the invention at roughly the same time;
- e. Whether others copied the invention;

- f. Whether there were changes or related technologies or market needs contemporaneous with the invention;
- g. Whether the invention achieved unexpected results;
- h. Whether others in the field praised the invention;
- i. Whether persons having ordinary skill in the art of the invention expressed surprise or disbelief regarding the invention;
- j. Whether others sought or obtained rights to the patent from the patent holder; and k. Whether the inventor proceeded contrary to accepted wisdom in the field.

[Source: The Federal Circuit Bar Association Model Patent Jury Instructions, § B.4.3(4.3c) (2014)].

**2.14 FALSE ADVERTISING – LIABILITY**

I will now instruct you how to decide whether or not Virtus falsely advertised its products.

Mission claims that Virtus engaged in false advertising. To succeed on this claim, Mission must prove five things by a preponderance of the evidence:

- (1) Virtus made a false or misleading statement of fact about its products;
- (2) Such statement either deceived, or had the capacity to deceive a substantial segment of Virtus's potential customers;
- (3) The deception is material, in that it is likely to influence Virtus's customers' purchasing decision;
- (4) The product is in interstate commerce; and
- (5) Mission has been or is likely to be injured as a result of the statement at issue.

If you find that Mission has proved each and all of these elements, then you must find for Mission. If, on the other hand, you find that Mission has failed to prove any one of these elements, then you must find for Virtus.

[Sources: SEVENTH CIRCUIT FEDERAL CIVIL JURY INSTRUCTIONS § 13.3.1 (2006); *Healthpoint, Ltd. v. Ethex Corp.*, No. Sa-01-Ca-646, 2004 WL 2359420, at \* 8 (W.D. 82 Tex. Jul. 4, 2004) (citing *Logan v. Burgers Ozark Country Cured Hams, Inc.*, 263 F.3d 447, 462 (5th Cir. 2001); *Pizza Hut, Inc. v. Papa Johns Int'l, Inc.*, 227 F.3d 489, 495 (5th Cir. 2000), *cert. denied*, 532 U.S. 920, 121 S.Ct. 1355 (2001); *Seven-Up Co. v. Coca-Cola Co.*, 86 F.3d 1379, 1383 n.3 (5th Cir. 1996); and *Taquino v. Teledyne Monarch Rubber*, 893 F.2d 1488, 1500 (5th Cir. 1990)).].

**2.15 DAMAGES - INTRODUCTION**

If you find that Virtus infringed any valid claim of the '247 patent or falsely advertised its products, you must then consider what amount of damages to award to Mission. I will now instruct you about the measure of damages. By instructing you on damages, I am not suggesting which party should win this case, on any issue.

First, I will address damages relating to infringement. The damages you award must be adequate to compensate Mission for the infringement. They are not meant to punish an infringer. Your damages award, if you reach this issue, should put Mission in approximately the same financial position that it would have been in had the infringement not occurred.

Mission has the burden to establish the amount of its damages by a preponderance of the evidence. In other words, you should award only those damages that Mission establishes that it more likely than not suffered.

There are different types of damages that Mission may be entitled to recover. In this case, Mission seeks lost profits, or alternatively, a reasonable royalty. Lost profits consist of any actual reduction in business profits Mission suffered as a result of Virtus's infringement. A reasonable royalty is defined as the money amount Mission and Virtus would have agreed upon as a fee for use of the invention at the time prior to when infringement began.

I will give more detailed instructions regarding damages shortly. Note, however, that Mission is entitled to recover no less than a reasonable royalty for each infringing sale.

[Source: The Federal Circuit Bar Association Model Patent Jury Instructions, § B.6(.1) (2014)].

#### 2.15.1 *Lost Profits – “But For” Test*

In this case, Mission seeks to recover lost profits for Virtus’s sales of Natalvirt CA, Natalvirt 90 DHA, and Natalvirt FLT.

To recover lost profits (as opposed to reasonable royalties), Mission must show a causal relationship between the infringement and Mission’s loss of profit. In other words, Mission must show that, but for the infringement, there is a reasonable probability that Mission would have earned higher profits. To show this, Mission must prove that, if there had been no infringement, it would have made some portion of the sales that Virtus made of the infringing products.

Mission is entitled to lost profits if it establishes each of the following:

(1) That there was a demand for the patented product.

(2) That there were no available, acceptable, noninfringing substitute products, or, if there were, its market share of the number of the sales made by Virtus that Mission would have made, despite the availability of other acceptable noninfringing substitutes.

(3) That Mission had the manufacturing and marketing capacity to make any infringing sales actually made by Virtus and for which Mission seeks an award of lost profits—in other words, that Mission was capable of satisfying the demand.

(4) The amount of profit that Mission would have made if Virtus had not infringed.

#### 2.15.2 *Lost Profits – Demand*

Demand for the patented product can be proven by significant sales of a patent holder’s patented product or significant sales of an infringing product containing the patented features.

#### 2.15.3 *Lost Profits – Noninfringing substitutes – Acceptability*

To be an “acceptable noninfringing substitute,” a product must have the advantages of the patented invention that were important to people who purchased an alleged infringer’s product. If purchasers of an alleged infringer’s product were motivated to buy that product because of features available only from that product and a patent holder’s patented product, then some other, alternative product is not an acceptable substitute, even if it otherwise competed with a patent holder’s and an alleged infringer’s products. On the other hand, if the realities of the marketplace are that competitors other than the patentee would likely have captured the sales made by the infringer, despite a difference in the products, then the patentee is not entitled to lost profits on those sales.

#### 2.15.4 *Lost Profits – Capacity*

A patent holder is only entitled to lost profits for sales it could have actually made. In other words, Mission must show that it had the manufacturing and marketing capability to make the sales it said it lost. This means Mission must prove it is more probable than not that it could have made and sold, or could have had someone else make or sell for it, the additional products it says it could have sold but for the infringement.

#### 2.15.5 *Lost Profits – Amount of Profit*

A patent holder may calculate its lost profits on lost sales by computing the lost revenue for sales

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it claims it would have made but for the infringement and subtracting from that figure the amount of additional costs or expenses it would have incurred in making those lost sales, such as cost of goods, sales costs, packaging costs, and shipping costs. Certain fixed costs that do not vary with increases in production or scale, such as taxes, insurance, rent, and administrative overhead, should not be subtracted from a patent holder's lost revenue.

[Source: The Federal Circuit Bar Association Model Patent Jury Instructions, § B.6(6.2) (2014)].

**2.15.6 *False Advertising Damages***

If you find that Virtus is liable to Mission for false advertising, then Mission may recover the profits Virtus gained from false advertising.

Profit is determined by deducting expenses from gross revenue. Gross revenue is all of the money Virtus received due to its false advertising.

Mission is required only to prove Virtus's gross revenue. Virtus is required to prove any costs or expenses that it argues should be deducted in determining its profits.

Mission is entitled to recover Virtus's total profits from its false advertising, unless Virtus proves that a portion of the profit is due to factors other than false advertising.

[Source: SEVENTH CIRCUIT FEDERAL CIVIL JURY INSTRUCTIONS § 13.6.4 (2006).].



2.15.1 ***Reasonable Royalty – Entitlement***

If you find that Mission has established infringement, Mission is entitled to at least a reasonable royalty to compensate it for that infringement. If you find that Mission has not proved its claim for lost profits, or has proved its claim for lost profits for only a portion of the infringing sales, then you must award Mission a reasonable royalty for all infringing sales for which it has not been awarded lost profits damages.

[Source: The Federal Circuit Bar Association Model Patent Jury Instructions, § B.6(6.5) (2014)].

2.15.2 ***Reasonable Royalty – Definition***

A royalty is a payment made to a patent holder in exchange for the right to make, use, or sell the claimed invention. A reasonable royalty is the amount of royalty payment that a patent holder and the infringer would have agreed to in a hypothetical negotiation taking place at a time prior to when the infringement first began. In considering this hypothetical negotiation, you should focus on what the expectations of the patent holder and the infringer would have been had they entered into an agreement at that time, and had they acted reasonably in their negotiations. In determining this, you must assume that both parties believed the patent was valid and infringed and the patent holder and infringer were willing to enter into an agreement. The reasonable royalty you determine must be a royalty that would have resulted from the hypothetical negotiation, and not simply a royalty either party would have preferred. Evidence of things that happened after the infringement first began can be considered in evaluating the reasonable royalty only to the extent that the evidence aids in assessing what royalty would have resulted from a hypothetical negotiation. Although evidence of the actual profits an alleged infringer made may be used to determine the anticipated profits at the time of the hypothetical negotiation, the royalty may not be limited or increased based on the actual profits the alleged infringer made.

[Source: The Federal Circuit Bar Association Model Patent Jury Instructions, § B.6(6.6) (2014)].

**2.15.3 Reasonable Royalty – Relevant Factors**

In determining the reasonable royalty, you should consider all the facts known and available to the parties at the time the infringement began, which in this case was January 25, 2013. Some of the kinds of factors that you may consider in making your determination are:

- (1) The royalties received by the patentee for the licensing of the patent-in-suit, proving or tending to prove an established royalty.
- (2) The rates paid by the licensee for the use of other patents comparable to the patent-in-suit.
- (3) The nature and scope of the license, as exclusive or nonexclusive, or as restricted or nonrestricted in terms of territory or with respect to whom the manufactured product may be sold.
- (4) The licensor's established policy and marketing program to maintain his or her patent monopoly by not licensing others to use the invention or by granting licenses under special conditions designed to preserve that monopoly.
- (5) The commercial relationship between the licensor and licensee, such as whether they are competitors in the same territory in the same line of business, or whether they are inventor and promoter.
- (6) The effect of selling the patented specialty in promoting sales of other products of the licensee, the existing value of the invention to the licensor as a generator of sales of his nonpatented items, and the extent of such derivative or convoyed sales.
- (7) The duration of the patent and the term of the license.
- (8) The established profitability of the product made under the patents, its commercial success, and its current popularity.
- (9) The utility and advantages of the patented property over the old modes or devices, if any, that had been used for working out similar results.
- (10) The nature of the patented invention, the character of the commercial embodiment of it as owned and produced by the licensor, and the benefits to those who have used the invention.
- (11) The extent to which the infringer has made use of the invention and any evidence probative of the value of that use.
- (12) The portion of the profit or of the selling price that may be customary in the particular business or in comparable business to allow for the use of the invention or analogous inventions.
- (13) The portion of the realizable profits that should be credited to the invention as distinguished from nonpatented elements, the manufacturing process, business risks, or significant features or improvements added by the infringer.
- (14) The opinion and testimony of qualified experts.
- (15) The amount that a licensor (such as the patentee) and a licensee (such as the infringer) would have agreed upon (at the time the infringement began) if both had been reasonably and voluntarily trying to reach an agreement; that is, the amount which a prudent licensee—who desired, as a business proposition, to obtain a license to manufacture and sell a particular article embodying the patented invention—would have been willing to pay as a royalty and yet be able to make a reasonable profit and which amount would have been acceptable by a prudent patentee who was willing to grant a license.

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No one factor is dispositive and you can and should consider the evidence that has been presented to you in this case on each of these factors. You may also consider any other factors which in your mind would have increased or decreased the royalty the infringer would have been willing to pay and the patent holder would have been willing to accept, acting as normally prudent business people. The final factor establishes the framework which you should use in determining a reasonable royalty, that is, the payment that would have resulted from a negotiation between the patent holder and the infringer taking place at a time prior to when the infringement began.

[Source: The Federal Circuit Bar Association Model Patent Jury Instructions, § B.6(6.7) (2014)].

## II. GLOSSARY

**Abstract:** A brief summary of the technical disclosure in a patent to enable the U.S. Patent and Trademark Office and the public to determine quickly the nature and gist of the technical disclosure in the patent.

**Amendment:** A patent applicant's change to one or more claims or to the specification either in response to an office action taken by an Examiner or independently by the patent applicant during the patent application examination process.

**Anticipation:** A situation in which a claimed invention describes an earlier invention and, therefore, is not considered new and is not entitled to be patented.

**Assignment:** A transfer of patent rights to another called an "assignee" who, upon transfer, becomes the owner of the rights assigned.

**Claim:** Each claim of a patent is a concise, formal definition of an invention and appears at the end of the specification in a separately numbered paragraph. In concept, a patent claim marks the boundaries of the patent in the same way that a legal description in a deed specifies the boundaries of land, i.e., similar to a landowner who can prevent others from trespassing on the bounded property, the inventor can prevent others from using what is claimed. Claims may be independent or dependent. An independent claim stands alone. A dependent claim does not stand alone and refers to one or more other claims. A dependent claim incorporates whatever the other referenced claim or claims say.

**Conception:** The complete mental part of the inventive act which must be capable of proof, as by drawings, disclosure to another, etc.

**Drawings:** The drawings are visual representations of the claimed invention contained in a patent application and issued patent, and usually include several figures illustrating various aspects of the claimed invention.

**Elements:** The required parts of a device or the required steps of a method. A device or method infringes a patent if it contains each and every requirement of a patent claim.

**Embodiment:** A product or method that contains the claimed invention.

**Enablement:** A description of the invention that is sufficient to enable persons skilled in the field of the invention to make and use the invention. The specification of the patent must contain such an enabling description.

**Examination:** Procedure before the U.S. Patent and Trademark Office whereby an Examiner reviews the filed patent application to determine if the claimed invention is patentable.

**Filing Date:** Date a patent application, with all the required sections, has been submitted to the U.S. Patent and Trademark Office.

**Infringement:** Violation of a patent occurring when someone makes, uses, or sells a patented invention, without permission of the patent holder, within the United States during the term of the patent.

**Limitation:** A required part of an invention set forth in a patent claim. A limitation is a requirement of the invention. The word "limitation" is often used interchangeably with the word "requirement."

**Nonobviousness:** One of the requirements for securing a patent. To be valid, the subject matter

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of the invention must not have been obvious to a person of ordinary skill in the field at the time of the earlier of the filing date of the patent application or the date of invention.

**Office Action:** A written communication from the Examiner to the patent applicant in the course of the application examination process.

**Patent:** A patent is an exclusive right granted by the U.S. Patent and Trademark Office to an inventor to prevent others from making, using, or selling an invention for a term of 20 years from the date the patent application was filed (or 17 years from the date the patent issued). When the patent expires, the right to make, use, or sell the invention is dedicated to the public. The patent has three parts, which are a specification, drawings and claims. The patent is granted after examination by the U.S. Patent and Trademark Office of a patent application filed by the inventor which has these parts, and this examination is called the prosecution history.

**Patent and Trademark Office (PTO):** An administrative branch of the U.S. Department of Commerce that is charged with overseeing and implementing the federal laws of patents and trademarks. It is responsible for examining all patent applications and issuing all patents in the United States.

**Prior Art:** Previously known subject matter in the field of a claimed invention for which a patent is being sought. It includes issued patents, publications, and knowledge deemed to be publicly available, such as trade skills, trade practices, and the like.

**Prosecution History:** The prosecution history is the complete written record of the proceedings in the PTO from the initial application to the issued patent. The prosecution history includes the office actions taken by the PTO and the amendments to the patent application filed by the applicant during the examination process.

**Reads On:** A patent claim “reads on” a device or method when each required part (requirement) of the claim is found in the device or method.

**Reduction to Practice:** The invention is “reduced to practice” when it is sufficiently developed to show that it would work for its intended purpose.

**Requirement:** A required part or step of an invention set forth in a patent claim. The word “requirement” is often used interchangeably with the word “limitation.”

**Royalty:** A royalty is a payment made to the owner of a patent by a nonowner in exchange for rights to make, use, or sell the claimed invention.

**Specification:** The specification is a required part of a patent application and an issued patent. It is a written description of the invention and of the manner and process of making and using the claimed invention.

**MISSION’S PROPOSED VERDICT FORM**

In answering these questions, you are to follow all of the instructions I have given you above. You may have to return to the instructions frequently as you answer these questions.

**I. QUESTION NO. 1 (INFRINGEMENT – LIABILITY)**

Did Mission prove that it is more probable than not that Virtus infringed claim 17 of the ‘247 patent? (Write a check or “x” next to yes **or** no).

Yes _____	No _____
(for Mission)	(for Virtus)

**II. QUESTION NO. 2 (INFRINGEMENT – WILLFULNESS)**

If you answered “Yes” to Question No. 1, did Mission prove that it is highly probably that Virtus’s infringement was willful? (Write a check or “x” next to yes **or** no).

Yes _____	No _____
(for Mission)	(for Virtus)

**III. QUESTION NO. 3 (INVALIDITY – INDEFINITENESS)<sup>3</sup>**

Did Virtus prove that it is highly probable that claim 17 of the ‘247 patent is invalid because the claim, viewed in light of the specification and prosecution history, fails to inform those skilled in the art about the scope of the invention with reasonable certainty? (Write a check or “x” next to yes **or** no).

Yes _____	No _____
(for Virtus)	(for Mission)

**IV. QUESTION NO. 4 (INVALIDITY – WRITTEN DESCRIPTION REQUIREMENT)**

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<sup>3</sup> The parties remain in discussions regarding the appropriateness of instructions related to indefiniteness. To the extent that any revisions are required the parties will submit them to the Court prior to the Pretrial Conference and to the extent any disagreements remain, the parties will indicate the same and be prepared to address their respective contentions at the Pretrial Conference.

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Did Virtus prove that it is highly probable that claim 17 of the ‘247 patent is invalid because a person having ordinary skill reading the original patent application would not have recognized that it describes the full scope of the claimed invention as it is finally claimed in the issued patent or that the inventor actually possessed that full scope by the filing date of the original application? (Write a check or “x” next to yes or no).

Yes \_\_\_\_\_ No \_\_\_\_\_  
(for Virtus) (for Mission)

V. **QUESTION NO. 5 (INVALIDITY – ENABLEMENT)**

Did Virtus prove that it is highly probable that claim 17 of the ‘247 patent is invalid because the specification does not contain enough information to have allowed a person having ordinary skill in the art to make and use the full scope of the claimed invention at the time the original patent application was filed? (Write a check or “x” next to yes or no).

Yes \_\_\_\_\_ No \_\_\_\_\_  
(for Virtus) (for Mission)

VI. **QUESTION NO. 6 (INVALIDITY - OBVIOUSNESS)**

Did Virtus prove that it is highly probable that claim 17 of the ‘247 patent is invalid because the subject matter of claim 17 as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art? (Write a check or “x” in the “Yes” or “No” column for each combination).

Combination of Prior Art References	Yes (for Virtus)	No (for Mission)
Ironate B Plus in view of the Hallberg reference, further in view of U.S. Patent No. 6,077,535 to Tiongson		
Ironate B Plus in view of the Hallberg reference, further in view of U.S. Patent No. 5,494,678 to Paradissis		
Ironate B Plus in view of the Sacks reference, further in view of U.S. Patent No. 6,077,535 to Tiongson		
Ironate B Plus in view of, the Sacks reference, further in view of U.S.		



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Patent No. 5,494,678 to Paradissis		
Ironate B Plus in view of the 1997 Federal Register Notice, further in view of U.S. Patent No. 6,077,535 to Tiongson		
Ironate B Plus in view of the 1997 Federal Register Notice, further in view of U.S. Patent No. 5,494,678 to Paradissis		

**VII. QUESTION NO. 7 (FALSE ADVERTISING – LIABILITY)**

Did Mission prove that it is more probable than not that Virtus falsely advertised its products?

Yes \_\_\_\_\_ No \_\_\_\_\_  
(for Mission) (for Virtus)

**VIII. QUESTION NO. 8 (DAMAGES)**

If you found claim 17 of the ‘247 Patent infringed (by answering “Yes” to Question No. 1) and not invalid (by answering “No” to Question No. 3, Question No. 4, and Question No. 5 and answering “No” for each combination of prior art references in Question No. 6), or if you found that Virtus falsely advertised its products (by answering “Yes” to Question No. 7), then answer this Question No. 8. Otherwise, do not answer any of the following questions.

**A. Lost Profits**

What lost profits, if any, did Mission show it more likely than not suffered as a result of sales of the accused products which Mission would with reasonable probability have made but for Virtus’s infringement or false advertising?

Lost Profits due to  
infringement or false  
advertising \$ \_\_\_\_\_

**B. Reasonable Royalty**

If you found claim 17 of the ‘247 Patent infringed (by answering “Yes” to Question No. 1) and not invalid (by answering “No” to Question No. 3, Question No. 4, and Question No. 5 and answering “No” for each combination of prior art references in Question No. 6), and if you found that Mission has not proved its claim for lost profits, or has proved its claim for lost profits for only a portion of the infringing sales, then answer the following question. Otherwise, do not answer any of the following questions.

What amount has Mission proved it is entitled to as a reasonable royalty for all infringing sales

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for which Mission has not been awarded lost profits damages?

Reasonable Royalty for  
infringement \$ \_\_\_\_\_  
Rate \_\_\_\_\_

Dated: September 3, 2014

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Respectfully submitted,

/s/ Charles B. Walker, Jr.

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**ATTORNEYS FOR PLAINTIFF MISSION  
PHARMACAL CO.**

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/s/ W. Scott Creasman

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